

CardioCoach Breathing Hose P/N 1TB0019 Instructions for Use

WARNING

The CardioCoach Breathing Hose is NOT a medical device. It is NOT intended to be used for the diagnosis or treatment of disease, and is only intended for use in non-medical applications.

Description and Specifications: The EVA Tubing consist of flexible, ribbed, medical grade, biocompatible plastic tubing with a smooth internal diameter of 1.2” and a length of 72”. The Breathing Hose has a smooth internal diameter and has integrated cuff on each end to interface with the CardioCoach device and Y-Valve.

Part Number	Tube Material	Temperature Limits	Cleaning	Disinfection	Sterilization	Use Type	Shelf Life
1TB0019	Clear EVA	-20° C to 70° C	Yes, see below	Yes, see below	NO	Multi-Patient Multi-Use	1 year

Intended Use: The CardioCoach Breathing Hose is used to transport the exhalations of subjects performing a VO2 Max test. A Y-Valve worn by the test subject allows the subject to breath in fresh air and directs the exhalations down the hose and into the CardioCoach Device. The product is supplied in clean, non-sterile condition.

Precautions: Grasp Hose by cuff and not the tube when disengaging from equipment. Follow CardioCoach directions for connection instructions. Modification or misuse may create a contamination risk or compromise structural integrity resulting in operational failure. Inspect tubing prior to and after installation for connection, leaks or degradation of performance. Kinking or collapse of tubing may result in restricted airflow or leakage. Replace tubing if discovered. Humidity, condensation, sharing with others and failure to comply with equipment manufacturers instructions for cleaning may lead to infection or cross infection and result in patient and/or healthcare staff exposure.

Warnings: Do not use chlorinated solutions, subject to prolonged exposure to ultraviolet (UV) light or exposure to conditions outside the limits. Damaged tubing needs to be replaced immediately to prevent leaks/inadvertent detachments. Skin irritation may occur if allergic to tube. Do not use if allergic. Do not use near sources of heat, like ovens, heaters, etc. Aerosol generation and risk of contamination of respiratory droplets with virus may be present if infection exists. Do not wrap around neck as this could lead to asphyxiation or strangulation.

Contraindications: This tubing is not for use on patients with the following conditions: excessive reflux, impaired cough reflex, or for off-label uses.

Adverse Events/ Side Effects: The following may occur: trouble getting used to wearing device, dry stuffy nose, feeling claustrophobic, difficulty falling asleep, dry mouth, irritation of the face/mask interface.

Cleaning – 52 cycles

Step	Parameters
Clean	Rinse the tubing under running utility (tap) water. Prepare a sink full of diluted mild detergent, such as dawn soap, in lukewarm tap water. Use approximately 2 ml of Dawn-soap per 1 L water. Immerse the articles into the detergent bath and allow to soak for a minimum of 1 minute. Rinse the tubing under running utility (tap) water to remove any visible detergent.
Dry	Dry and Inspect Hang and allow to fully air dry. Visually inspect the tubing for any damage or discoloration – Discard if you notice any damages or discoloration.

Disinfection – 52 cycles

Step	Parameters
Prep	Conduct Cleaning as outlined above. Prepare a sink full of water (tap water) with a temperature of at least 70°C.
Disinfect	Submerge the tubing into the water for at least 30 minutes. Be sure to get all bubbles out from inside of the tube.
Rinse	Remove and rinse thoroughly with distilled water.
Dry	Dry and Inspect Hang and allow to fully air dry. Visually inspect the tubing for any damage or discoloration – Discard if you notice any damages or discoloration.

For any question related to this product, please contact KORR Medical Technologies, Inc.